



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2014-0219; FRL-9907-92]

Pesticides; Consideration of Volatilization in Pesticide Risk Assessment: Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the availability of several draft guidance documents for public comment. These documents detail EPA's approach in developing a pesticide volatilization screening methodology for human health. Once final, these guidance documents will be posted on EPA's website, to promote consistent risk assessment practices and provide transparency for pesticide registrants and other interested stakeholders.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2014-0219, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Health Effects Division (7507P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-0291; email address: smith.charles@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What is the Agency's Authority for Taking this Action?

Pesticides are regulated under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et. seq.*, and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a.

B. Does this Action Apply to Me?

You may be potentially affected by this action if you are a producer of pesticide products (NAICS code 32532), importers of such products, or any person or company who seeks to obtain a tolerance for such a pesticide. The North American Industrial Classification System (NAICS) code is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Other types of entities not listed could also be affected.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

D. What Action is the Agency Taking?

Volatilization of a pesticide can be characterized as the physical movement of the vapor phase of a pesticide through the air after an application has occurred from the target site to any non- or off-target site. This does not include pesticide movements by spray drift, erosion, migration, or windblown soil particles after application.

Volatilization is dependent on a number of physical and chemical properties, weather conditions, and other factors. Once off-target, pesticide volatilization can result in inhalation exposure to people, such as bystanders.

EPA has developed a guidance document describing EPA's approach in developing a volatilization screening methodology for human health. The “Human Health Bystander Screening Level Analysis: Volatilization of Conventional Pesticides” document (and its appendices) describes the development of the screening tool, the guiding principles behind the screening tool, the various inputs utilized in the screening tool, and the results of the screening analysis that EPA has recently completed using this methodology.

These documents are available in the docket for this action using the docket ID number EPA-HQ-OPP-2014-0219 (Refs. 1, 2, 3, 4, and 5). These policies will promote consistency within EPA, as well as with other Federal agencies and international regulatory partners that consider volatilization for pesticides.

II. Consideration of Volatilization in Human Health Risk Assessment

Over many years, EPA has been actively engaged in evaluating possible exposures associated with air borne, off-target movement of pesticides. EPA has worked to develop and refine its methodologies for assessing bystander inhalation exposures resulting from volatilization of fumigants as well as to spray drift from the application of conventional pesticides in agricultural settings. Recently, EPA published a notice for comment in the **Federal Register** of January 29, 2014 (79 FR 4691) (FRL-9903-12) two draft guidance documents describing how EPA plans to evaluate off-site spray drift for ecological and human health risk assessments. These documents are available at [regulations.gov](http://www.regulations.gov) using the docket ID number EPA-HQ-OPP-2013-0676.

To account for volatilization from non-fumigant uses, EPA has been adapting the approaches developed for conducting risk assessments for the fumigants in assessing potential bystander inhalation risk. Notable milestones in this effort include the 2009 FIFRA Scientific Advisory Panel (SAP) review of issues related to volatilization of conventional pesticides (Ref. 6) and the 2013 chlorpyrifos preliminary volatility assessment (Ref. 7).

These adaptations have resulted in a Volatilization Screening Tool that provides a consistent and health protective framework to assess the potential inhalation bystander risks resulting from volatilization of conventional pesticides. A Volatilization Screening Tool Guidance Document (Ref. 2) was produced to support the screening tool. To estimate potential bystander inhalation risks, the screening tool uses:

- A number of physical and chemical properties to predict flux (i.e., the rate at which a chemical volatilizes off of a treated field).

- The AERSCREEN model (Ref. 8) to estimate air concentrations at different distances from a treated field.

- Chemical-specific human health toxicological data.

Four of the draft documents (Refs. 1, 2, 3, and 4) provide details on the volatilization screening methodology including the development of the screening tool, the guiding principles behind the screening tool, and the various inputs used in the screening tool. To demonstrate the application of this methodology, two documents (Refs. 1 and 5) present the results of the screening analysis that EPA completed using this methodology which examined all of the conventional pesticides being evaluated in the Registration Review process. It is important to note that “failing” the screening analysis does not necessarily mean that the pesticide poses a risk of concern due to volatilization. Rather, due to the purposely conservative nature of the screening analysis, failing the screen is merely a trigger for the Agency to further investigate the question of exposure from volatilization of the pesticide.

III. References

As indicated under **ADDRESSES**, a docket has been established for this notice under docket ID number EPA-HQ-OPP-2014-0219. The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Human Health Bystander Screening Level Analysis: Volatilization of Conventional Pesticides (Draft dated 3/1/2014).
2. EPA. Appendix A: Volatilization Screening Tool Guidance Document (Draft dated 3/1/2014).
3. EPA. Appendix B: Inhalation Equivalent Concentration Calculations for the Registration Review Chemical Analysis (Draft dated 3/1/2014).
4. EPA. Appendix C: Data Entry Sheets for the Registration Review Chemical Volatilization Screening Analysis (Draft dated 3/1/2014).
5. EPA. Appendix D: Registration Review Chemical Volatilization Screening Analysis Results (Draft dated 3/1/2014).
6. FIFRA SAP. December 1-4, 2009: Scientific Issues Associated with Field Volatilization of Conventional Pesticides. Available at <http://www.epa.gov/scipoly/sap/meetings/2009/120109meeting.html> (accessed 2/24/2014), or in the docket at regulations.gov using the document ID number EPA-HQ-OPP-2009-0687).
7. EPA. Chlorpyrifos Preliminary Evaluation of the Potential Risks from Volatilization: Available in the docket at regulations.gov using the document ID number EPA-HQ-OPP-2008-0850-0114).
8. EPA. Technology Transfer Network Support Center for Regulatory Atmospheric Modeling: Preferred/recommended Models. Available at http://www.epa.gov/ttn/scram/dispersion_prefrec.htm (accessed 2/26/2014).

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: March 18, 2014.

Marty Monell, Acting

Director, Office of Pesticide Programs.

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